

**NATIONAL INSTITUTES OF HEALTH
RECOMBINANT DNA ADVISORY COMMITTEE (RAC)**

106th Meeting

**NIH Campus
Building 31, Sixth Floor, C Wing, Room 10**

**December 5-6, 2006
Agenda**

Tuesday, December 5, 2006

12:15 PM Call to Order and Opening Remarks

Howard Federoff, M.D., Ph.D., Chair, NIH RAC

Tab 2429 For Your Information
 Notice of Meeting
 Conflict of Interest Guidance

12:20 PM Minutes of the September 20, 2006, RAC Meeting

RAC Reviewers: Nikunj Somia, Ph.D.
 David Weber, M.D., M.P.H.

Tab 2430 Minutes of the September 20, 2006, RAC Meeting

12:30 PM Gene Transfer Safety Assessment Board Report

Tab 2431 Response to M-I-C-1
 Protocol List
 Protocols Not Selected for RAC Public Review

RAC Reviewers: Steven Albelda, M.D.
 Howard Federoff, M.D., Ph.D.
 Helen Heslop, M.D.

**12:50 PM FDA Guidance on Testing for Replication Competent Adenovirus in
Adenoviral Vector-Based Gene Transfer**

Speaker: Daniel Takefman, Ph.D.
 U.S. Food and Drug Administration

Moderator: Richard Vile, Ph.D.

Tuesday, December 5, 2006 (continued)

Tab 2432 Excerpt from FDA Draft Guidance for Review Staff and Sponsors:
*Content and Review of Chemistry, Manufacturing, and Control
(CMC) Information for Human Gene Therapy Investigational New
Drug Applications*

1:00 PM **Discussion of Human Gene Transfer Protocol #0610-807:** *A Phase I Trial of
Intratumoral Administration of Secondary Lymphoid Chemokine Gene-Modified
Autologous Dendritic Cells in Advanced Non-Small Cell Lung Cancer*

PI: Steven M. Dubinett, M.D., UCLA School of Medicine, Los Angeles, CA

RAC Reviewers: Glen Nemerow, Ph.D.
 Scott Strome, M.D.
 Ellen Grant, Ph.D., LSCW-R
 Richard Vile, Ph.D.

Tab 2433 Protocol

Tab 2434 OBA Summary
 OBA Letter to PI on In-Depth RAC Review and
 Public Discussion
 Reviews from Drs. Nemerow, Strome, Grant, and Vile
 PI's/Sponsor's Response

2:45 PM Public Comment

3:00 PM **ADJOURNMENT**

Wednesday, December 6, 2006

8:30 AM **Call to Order and Opening Remarks**

Howard Federoff, M.D., Ph.D., Chair, NIH RAC

8:35 AM **Discussion of Human Gene Transfer Protocol #0607-784:** *A Phase I, Open-
Label, Dose-Escalation, Pharmacodynamic Study of Intranodal Injection of
Adenovirus-CD154 (Ad-ISF35) in Patients with Chronic Lymphocytic
Leukemia/Small Lymphocytic Lymphoma*

PI: Januario E. Castro, M.D., Moores UCSD Cancer Center, La Jolla, CA

RAC Reviewers: Stephen Dewhurst, Ph.D.
 Helen Heslop, M.D.
 Eric Kodish, M.D.

Wednesday, December 6, 2006 (continued)

Tab 2435 Protocol

Tab 2436 OBA Summary
OBA Letter to PI on In-Depth RAC Review and
Public Discussion
Reviews from Drs. Dewhurst, Heslop, and Kodish
PI's/Sponsor's Response

10:20 AM Public Comment

10:30 AM **BREAK**

10:45 AM **Discussion of Human Gene Transfer Protocol #0610-813: *A Pilot Study of Genetically Modified Haploidentical Natural Killer Cell Infusions for B-Lineage Acute Lymphoblastic Leukemia***

PI: Dario Campana, M.D., Ph.D., St. Jude Children's Research Hospital,
Memphis, TN

RAC Reviewers: Steven Albelda, M.D.
Hildegund Ertl, M.D.
Robyn Shapiro, J.D.

Ad hoc Reviewer: Terry J. Fry, M.D., National Cancer Institute, National
Institutes of Health, Bethesda, MD

Tab 2437 Protocol

Tab 2438 OBA Summary
OBA Letter to PI on In-Depth RAC Review and
Public Discussion
Reviews from Drs. Albelda and Ertl; Ms. Shapiro; and Dr. Fry
PI's/Sponsor's Response

12:30 PM **Public Comment**

12:45 PM **LUNCH**

1:30 PM **Discussion of Human Gene Transfer Protocol #0610-810: *A Phase I, Open-Label, Rising-Dose Study of the Safety and Tolerability of Single Doses of NUC B1000, an RNAi-Based Therapy for Chronic Hepatitis B***

PI: Robert G. Gish, M.D., California Pacific Medical Center, San Francisco,
CA

Submitter: C. Satishchandran, Ph.D., Nucleonics Inc., Horsham, PA

Wednesday, December 6, 2006 (continued)

RAC Reviewers: Stephen Dewhurst, Ph.D.
Jeffrey Kahn, Ph.D., M.P.H.
Louis Kirchhoff, M.D., M.P.H.

Ad hoc Reviewers: Natasha Caplen, Ph.D., National Cancer Institute, National
Institutes of Health, Bethesda, MD

T. Jake Liang, M.D., National Institute of Diabetes and
Digestive and Kidney Diseases, National Institutes of
Health, Bethesda, MD

Tab 2439 Protocol

Tab 2440 OBA Summary
OBA Letter to PI on In-Depth RAC Review and
Public Discussion
Reviews from Drs. Dewhurst, Kahn, Kirchhoff, Caplen, and Liang
PI's/Sponsor's Response

3:15 PM Public Comment

3:30 PM **ADJOURNMENT**